Remarks

Status of Claims:

Claims 1, 4, 8-20 are rejected. Claims 1, 9, 10, 11, and 16 are amended. Claims 1, 4, 8-20 remain pending.

The amendments are supported by the application and drawings as filed. No new matter is added.

112 Rejection:

The Examiner is requested to withdraw the 112 rejection in view of the amendment to claim 1.

102 and 103 Rejections:

Claims 16-19 are rejected as anticipated by US 6,758,824 (Miller). Claims 1, 4, 8, 9-14, 15, and 20 are rejected as obvious over Miller in combination with other references. It is respectfully urged that this rejection is improper for at least the following reasons.

In rejecting Claim 16-19, as anticipated by Miller, and the other pending Claims as obvious with respect to Miller, the Examiner refers to Fig 3A of Miller, and the Examiner states Miller shows:

> The device comprises a *distal* needle segment 50 as shown in Figure 3A. The *distal* needle segment has a lateral tissue receiving port 55 and is *distal* from the target site when the device is in operation. (italics added)

It is respectfully urged the Examiner has mischaracterized and misapplied Miller on a number of points.

First, Miller actually teaches element 50 is an "aspiration tube 50", and that element 55 is a "collection trap 55". It is respectfully urged that element 55 of Miller is not a "lateral tissue receiving port." To the extent Miller has a lateral tissue receiving port, it would be the tissue receiving opening 25 shown in Figure 3A and described at column 6, lines 31-41 of Miller.

Second, the Examiner's statement that Miller teaches that the tissue receiving port 55 is distal of the target site when the device is in operation does not seem to be consistent with Miller's disclosure. The Examiner is requested to explain how the element 50 or the element 55 of Miller can be distal of a target site within the patient.

Third, with respect to amended Claims 1 and 16, it is respectfully urged that Miller's collection trap 55, even if it were assumed to be a "lateral tissue receiving port", is not positionable in a patient, and that the Examiner may not properly apply the collection trap 55 as being a "lateral tissue receiving port" as that phrase is used in Applicant's amended Claims 1 and Claim 16.

Fourth, the Examiner's rejection of all the pending claims relies on an incorrect reference to proximal portions of Miller as "distal", and distal portions of Miller as "proximal." As noted above, the Examiner's rejection includes the following reasoning:

> The device comprises a *distal* needle segment 50 as shown in Figure 3A. The *distal* needle segment has a lateral tissue receiving port 55 and is *distal* from the target site when the device is in operation. (italics added)

This construction of "proximal" and "distal" by the Examiner is contrary to the teachings of Miller. Miller at column 21, claim 1, Claim 1 recites:

> ….an inner cannula slidably disposed within said outer lumen and defining a inner lumen from an open *distal end* to an open *opposite proximal end*, said inner cannula defining a cutting edge at said *open distal end* operable to sever tissue projecting through said tissue receiving opening;…." (italics added)

Miller at column 22, claim 7 also recites:

> "..a collection trap removably mountable to said handpiece and in communication with said *proximal end* of said inner lumen." (italics added)

So, not only does Miller's own text show the Examiner has misconstrued element 55 of Miller as a lateral tissue receiving port, but this text from Miller also indicates the directions "proximal" and "distal" as used in Miller are opposite to the Examiner's interpretation in stating that

elements 50 and 55 of Miller are distal from a target site. Further, the Examiner's statement in the most recent rejection that element 15 of Miller is a "proximal needle segment" while element 50 of Miller is a "distal needle segment" seems to completely reverses the meaning of the words proximal and distal as those words are used in Miller.

Fourth, Claims 1 and 16 as amended recites a tissue piercing tip associated with the distal end of the distal needle segment, where the lateral tissue receiving port of the distal needle segment is disposed proximal of the piercing tip. It is respectfully urged that even if one where to (incorrectly) adopt the Examiner's interpretation of "proximal" and "distal", Miller still would not anticipate or render obvious claims 1 or 16, because Miller does not have a tissue piercing tip associated with a distal end of what the Examiner calls "distal needle segment (50)". To the extend Miller has a tissue piercing tip, it is "trocar tip" 16. See Fig 3A of Miller.

Claim 19:

Claim 19 recites, among other things:

> a distal needle segment formed of a non-metallic material and having a lateral tissue receiving port communicating with a distal cutter lumen segment....
> a metallic proximal needle segment disposed proximally of the tissue receiving port,
> .....
> wherein the distal end of the proximal needle segment is positioned distally of the proximal end of the distal needle segment.

The Examiner's rejection of Claim 19 as anticipated by Miller is improper for at least the reasons provided above with respect to Claims 1 and 16.

Further, Miller does not teach or suggest a distal end of a metallic proximal needle segment positioned distally of a proximal end of a distal needle segment formed of a non-metallic material and having a lateral tissue receiving port.

Claim 9:

Claim 9 recites among other things

> the cutter lumen and the vacuum lumen extend generally side by side along at least a portion of the length of the cutter lumen.

It is respectfully urged that the references cited by the Examiner do not teach or suggest a vacuum lumen, little less the cutter lumen and vacuum lumen as recited.

Claim 14

The Examiner states Miller discloses a continuous lumen comprising at least one passage extending to an outer surface of the needle. However, the Examiner does not indicate where this teaching in Miller occurs. The Examiner's only explanation is:

> "Miller et al. disclose the continuous lumen formed by the distal needle portion and the proximal needle portion creates a vacuum lumen and allows vacuum pressure to be maintained….(col 8, lines 26-60). The lumen comprises at least one passage extending to an outer surface of the needle….."

Column 8, lines 26-60 of Miller do not appear to teach or suggest a vacuum lumen. Instead, lines 26-60 of Column 8 of Miller disclose features such as: rotary and reciprocating motion of inner cannula 17, that every component of the apparatus with the exception of outer cannula 15, trocar tip 16 and inner cannula 17 can be formed of a non-metallic material, that the device may be used with MRI, that the entire device can be disposable, that elimination of substantially all metal components reduces weight of the handpiece 12, that the pneumatic cylinder 60 includes a pilot port, that motor 22 includes a piston 63, that piston 63 includes a bore 64 for mounting piston 63 to the aspiration tube 50, and that it is essential that the tube 50 and piston 63 move together, since motor 22 must drive inner cannula 17 axially within the outer cannula.

So, not only has the Examiner mischaracterized what column 8, lines 26-60 of Miller teaches, this portion of Miller contradicts some of the very positions the Examiner takes in rejecting other claims!!!

The Examiner is respectfully requested to explain in a clear manner how column 8, lines 26-60 of Miller supports the Examiner's various positions in rejecting the claims.

It is respectfully urged that Miller does not teach or suggest a vacuum lumen, and so fails to teach or suggest the subject matter of Claim 14 or Claim 15.

If the Examiner disagrees, the Examiner should point out specifically where in Miller a vacuum lumen is disclosed, and where there is a teaching or suggestion that one provide at least one passage extending from the vacuum lumen to an outer surface of a needle.

As explained in the last response, the Examiner has taken similar unsupported positions in prior rejections. For instance, in a prior rejection the Examiner has stated:

"The distal needle segment of the Miller et al device includes a tissue receiving port(43) and is made of non-metallic material…." Citing col 8, lines 22-60 of Miller.

As explained above (and in a previous response), this is not a correct characterization of the cited portion of Miller Instead, Column 8, lines 22-60 of Miller state:

> "In fact, with the exception of outer cannula 15, trocar tip 16 and inner cannula 17, every component of the biopsy apparatus in accordance with the present invention can be formed of a non-metallic material…." (underlining added)

Accordingly, the portions of Miller cited by the Examiner do not support the rejection previously, or in the most recent rejection. Instead, Miller teaches away from proximal and distal needle segments as claimed.

Prior to rejection any of the claims in another office action, the Examiner is *respectfully requested to carefully read Miller, and to carefully and clearly set forth how Miller teaches the subject matter of the Claim*s, using the terms distal and proximal in a manner that is consistent with the use of those terms in Miller.

Obviousness Rejections:

It is respectfully urged that each of the obviousness rejections is improper for at least the reason that each obviousness rejection is based upon the Examiner's incorrect application of Miller, as explained above.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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